THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 53 (90/003,486)
Paper No. 39 (90/003,988)

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte NOVAMEDIX LIMITED

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Appeal No. 97-2135
Reexamination Control Nos. 90/003,486 and 90/003,988[1]

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HEARD: November 14, 1997

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Before CALVERT, McQUADE and CRAWFORD, Administrative Patent Judges.

McQUADE, Administrative Patent Judge.

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[1] Requests filed July 11, 1994 (Control No. 90/003,486) and October 4, 1995 (Control No. 90/003,988) by Kinetic Concepts, Inc. for the reexamination of U.S. Patent No. Re. 32,939, issued June 6, 1989, based on Application 07/194,438, filed May 16, 1988. The resulting reexamination proceedings were ordered merged on February 1, 1996 (see Paper No. 17 in Control No. 90/003,486 and Paper No. 8 in Control No. 90/003,988). U.S. Patent No. Re. 32,939 is a reissue of U.S. Patent No. 4,614,180, issued September 30, 1986, based on Application 06/763,686, filed August 8, 1985. According to the appellant, Application 06/763,686 is a continuation-in-part of Application 06/621,499, filed June 18, 1984, now abandoned.

DECISION ON APPEAL

Novamedix Limited appeals from the examiner's final rejection of claims 7 through 9 and 11 in these merged reexamination proceedings involving U.S. Patent No. Re. 32,939. The examiner has found the subject matter recited in claims 1 through 6 and 12 through 32, the only other claims pending in the merged proceedings, to be patentable. Our decision in this appeal applies to each proceeding.

The record indicates that U.S. Patent No. Re. 32,939, as well as related and commonly assigned U.S. Patents Nos. Re. 32,940, 4,696,289 and 4,721,101, are currently the subject of litigation, styled Novamedix, Ltd. v. Kinetic Concepts, Inc. and KCI New Technologies, Inc., Civil Action No. SA-92-CA-1077, in the United States District Court for the Western District of Texas, San Antonio Division.[2] The record also indicates that these four patents had been the subject of litigation, styled Novamedix Limited v. NDM Acquisition Corp. et al., Civil Action No. C-3-94-251, in the United States District Court for the Southern District of Ohio, Western Division at Dayton. In the latter case, the court

[2] Kinetic Concepts, Inc. also has requested two reexaminations in each of U.S. Patent Nos. Re. 32,940, 4,696,289 and 4,721,101. Control Nos. 90/003,487 and 90/003,987 for U.S. Patent No. Re. 32,940 have resulted in the issuance on December 3, 1996 of Reexamination Certificate B1 Re. 32,940. Control Nos. 90/003,488 and 90/003,989 for U.S. Patent No. 4,696,289 are currently on appeal to this Board (Appeal No. 97-3680). Control Nos. 90/003,489 and 90/003,990 for U.S. Patent No. 4,721,101 also are currently on appeal to this Board (Appeal No. 97-2766).

entered a final judgment on consent decreeing, inter alia, that each of the claims in the four patents "is valid and enforceable" (see Paper No. 19 in Control No. 90/003,486 and Paper No. 10 in Control No. 90/003,988).

The invention at issue in the instant appeal relates to an "apparatus for artificially stimulating the venous-return flow of blood from the foot by inducing sharply pulsed squeezing or necking-down of the vessels of the venous-pump mechanism within the foot" (Patent Abstract). The inventors, Arthur M. N. Gardner and Roger H. Fox, claim to "have discovered a venous pump mechanism in the sole of the human foot, which under normal walking conditions for the foot, serves to return blood from the leg into the abdomen with no assistance from muscular action" (patent specification, column 1, lines 42 through 46). Their apparatus stimulates this physiological venous pump mechanism by operating in accordance with criteria specifically chosen to simulate forces applied to the foot under normal ambulatory conditions (see, for example, the patent specification at column 1, lines 42 through 55; column 2, line 45 through column 3, line 2; and column 7, line 10 through column 8, line 43). Claim 7 is illustrative and reads as follows:

> 7. A medical appliance comprising an inflatable bag shaped for active engagement solely with a human foot and substantially only in the region between the ball and the heel of the foot, and cyclically operable automatic means for delivering pressure within said bag in accordance with the following criteria:
>
> (a) a pressure rise to a predetermined maximum of 220-mm [mg] Hg or less within less than two seconds;

(b) upon achievement of said maximum, dropping the pressure at least to one seventh of said maximum pressure within approximately one second; and

(c) repeating pressure delivery pursuant to criteria (a) [a] and (b) [b] at a periodic interval which is in the range of 5 to 60 seconds.

The prior art references relied upon by the examiner as evidence of obviousness are:

Nicholson et al. (Nicholson)	3,901,221	Aug. 26, 1975
Dreiser, French Patent Document[3]	2,390,156	Dec. 8, 1978

Gaskell, P. and Parrott, J. C. W., "The Effect of a Mechanical Venous Pump on the Circulation of the Feet in the Presence of Arterial Obstruction," Surgery, Gynecology & Obstetrics, Volume 146, pages 583-592, April 1978 (Gaskell/Parrott)

Claims 7 through 9 and 11 stand rejected under 35 U.S.C. § 103 as being unpatentable over Dreiser in view of Gaskell/Parrott or Nicholson.

Reference is made to the appellant's main and reply briefs (Paper Nos. 29 and 34 in Control No. 90/003,486; and Paper Nos. 19 and 23 in Control No. 90/003,988) and to the examiner's final rejection and answer (Paper Nos. 26 and 31 in Control No. 90/003,486; and Paper Nos. 16 and 21 in Control No. 90/003,988) for the respective positions of the appellant and the examiner with regard to the merits of this rejection.

In addition to arguing the merits of the foregoing rejection, the appellant raises as issues in this appeal the propriety of (1) the Commissioner's grant of the second request for reexamination (Control No. 90/003,988); and (2) the examiner's decision in the first

[3] The record in each of the reexamination proceedings contains an English language translation of the Dreiser reference.

reexamination proceeding (Control No. 90/003,486, Paper No. 20) to withdraw the finality of the Office action dated November 2, 1995 (see, for example, pages 9 and 34 through 40 in the main brief and pages 5 through 15 in the reply brief). These matters, however, are not directly connected with the merits of issues involving a rejection of claims.[4] Therefore, they are reviewable by petition to the Commissioner rather than by appeal to this Board. See In re Hengehold, 440 F.2d 1395, 1403-1404, 169 USPQ 473, 479 (CCPA 1971). Indeed, the record indicates that the appellant's arguments relating to these matters have been treated and duly reviewed as a petition to the Commissioner under 37 CFR § 1.181 (see Paper No. 33 in Control No. 90/003,486; and Paper No. 22 in Control No. 90/003,988). Accordingly, we shall not review or further discuss same.

Turning now to the standing 35 U.S.C. § 103 rejection of claims 7 through 9 and 11, it is axiomatic that in rejecting a claim, an examiner bears the initial burden of presenting a factual basis establishing a prima facie case of unpatentability. In re Oetiker, 977 F.2d 1443, 1445-46, 24 USPQ2d 1443, 1444-45 (Fed. Cir. 1990); In re Piasecki, 745 F.2d 1468, 1471-72, 223 USPQ 785, 788 (Fed. Cir. 1984). If this burden is met, the burden of

[4] In disputing the Commissioner's grant of the second request for reexamination, the appellant does not assert or imply that the 35 U.S.C. § 103 rejection on appeal is procedurally inconsistent with the reexamination statute or the interpretation thereof set forth by the Court of Appeals for the Federal Circuit in In re Portola Packaging, Inc., 110 F.3d 786, 42 USPQ2d 1295 (Fed. Cir. 1997); and In re Recreative Technologies Corp., 83 F.3d 1394, 38 USPQ2d 1776 (Fed. Cir. 1996). See also In re Hiniker Co., 150 F.3d 1362, 47 USPQ2d 1523 (Fed. Cir. 1998).

coming forward with a showing of facts supporting the opposite conclusion shifts to the applicant. After such rebuttal evidence is submitted, all of the evidence must be considered anew, with patentability being determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument. Of course, if the examiner's initial showing does not produce a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent. Id.

With regard to rejections made under 35 U.S.C. § 103, our reviewing court stated in In re Huang, 100 F.3d 135, 139, 40 USPQ2d 1685, 1687-88 (Fed. Cir. 1996):

> A claimed invention is unpatentable if the differences between it and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103 (1994). The ultimate determination as to whether or not an invention is obvious is a legal conclusion based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 USPQ 459, 567 (1966).

Within this framework, the test for obviousness is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re Keller, 642 F.2d 413, 425-26, 208 USPQ 871, 881-82 (CCPA 1981). A conclusion of obviousness may be based on the common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference. In re Bozek, 416 F.2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969). In this regard, skill is to be

presumed on the part of the artisan. In re Sovish, 769 F.2d 738, 743, 226 USPQ 771, 774 (Fed. Cir. 1985).

Dreiser, the examiner's primary reference, discloses a "pressotherapy" boot for applying pressure and decompression to the leg of a patient to treat circulatory insufficiencies (see page 1 in the translation). To this end, the boot includes a plurality of inflatable pockets 1 through 4, each corresponding to a segment of the patient's leg and having a respective plug or fitting 5 for connection to a source of pressurized air such as a compressor. Pocket 1 corresponds to the thigh, pocket 2 to the calf, pocket 3 to the ankle, and pocket 4 to the sole of the foot "in the region where arterial and venous intersections are very dense" (translation, page 3). Dreiser's drawings indicate that pocket 4 is shaped for active engagement with the patient's foot substantially only in the region between the ball and the heel of the foot.

The examiner's determination that Dreiser teaches, or would have suggested, a medical appliance meeting all of the limitations in claims 7 through 9 and 11 except for those relating to the specific operational criteria of the cyclically operable automatic means for delivering pressure within the bag (see pages 3 and 4 in the final rejection) is well founded. In this regard, Dreiser's pocket 4 constitutes an inflatable bag shaped for active engagement solely with a human foot and substantially only in the region between the ball and heel of the foot, and Dreiser's source of pressurized air for applying pressure and

decompression is suggestive of a cyclically operable automatic means for delivering pressure within this bag. The appellant's argument that the examiner's determination here is unsound because the Dreiser apparatus involves a boot-like structure and includes additional pockets 1, 2 and 3 is not persuasive because it is not commensurate with the actual scope of the appealed claims. As pointed out by the examiner (see page 5 in the answer), none of the appealed claims contains any limitation which is inconsistent with or excludes the presence of a boot-like structure or additional pockets or bags.

Be this as it may, however, the examiner's reliance on Gaskell/Parrott or Nicholson to cure the acknowledged deficiencies of Dreiser with respect to the claimed invention is not well taken.

Gaskell/Parrott discloses a mechanical venous pump for treating severe arterial obstructions in a patient's foot. As described in this reference,

> [t]he venous pump consisted of the arrangement illustrated in Figure 1. The foot, covered by a length of stockinette, was inserted into a boot made of a single layer of transparent flexible vinyl plastic sheet. The toe of the boot was fitted with a large metal ring which was made airtight by the insertion of a rubber stopper. The stopper carried tubes for the inflation of the boot and for monitoring pressures. At the ankle, the boot was circled by a pneumatic cuff shaped to fit snuggly on a cone. The cuff and the boot were connected to their own individual air pressure reservoirs. To operate the pump, the cuff was first inflated to the pressure desired in the boot. The pressure reservoir serving the boot was then opened with an available pressure above that in the cuff. The boot was quickly inflated to the pressure set by the pressure in the cuff, with the excess flow of air escaping from the boot under the cuff. Both cuff and boot were deflated again after 2 seconds. The pressure on the foot within the boot was thus regulated by the pressure in the cuff. An

> electronic timer controlled the time and period of inflation of the cuff or boot individually but in a linked and synchronized manner [page 583].

According to Gaskell/Parrott, "[a] brief inflation of the boot empties the veins of the foot, and the venous pressure remains reduced until the veins are refilled by forward flow of blood from the arteries" (page 583). To evaluate the effectiveness of the boot in reducing venous pressure, Gaskell/Parrott tested it using the following variables: "compression pressures, ranging from 40 millimeters of mercury below to 40 millimeters of mercury above the venous pressure at the foot, compression periods of 0.5 to 4.0 seconds in increments of 0.5 second, compression frequencies of once every 5, 10, 15, 20 and 30 seconds" (page 584). Figure 3 depicts the results of tests using different compression pressures wherein "the foot was compressed every 15 seconds for 2 seconds" (page 586). Among other things, Gaskell/Parrott generally found

> that a compression pressure several millimeters of mercury higher than the maximum venous pressure at the foot was necessary for most efficient pressure reduction. A compression period of 2 seconds was the minimum at which one could be sure of an adequate pressure reduction, 1 second was often too short and periods longer than 2 seconds were unnecessary and reduced efficiency [pages 587 and 588].

Nicholson discloses a boot for treating circulatory deficiencies in a patient's leg in order to increase the flow of blood through the veins. According to Nicholson, this result can be obtained "by applying pressure through a pressure garment with a rise time of at least 10 mm of mercury per second and a holding time at the level of at least 30 mm of

mercury for at least 8 seconds. A cycle period of one minute is near optimum" (column 1, lines 51 through 55). The boot 26 communicates with a pressure tank 30 via hoses 28. The operation of the boot is controlled by a cyclic controller 34 for applying and releasing pressure in accordance with the graph shown in Figure 1. As described by Nicholson,

> FIG. 1 is a graph of pressure at the cyclic controller output in accordance with the preferred pressure cycle. When the pressure line is connected to the boot by operation of a valve at time zero, curve portion 10 indicates a rapid rise in less than 4 seconds to greater than 30 mm of mercury. The pressure then climbs gradually above 40 mm of mercury as indicated by curve 11 until 10 seconds is reached at which point the pressurizing valve is closed and the exhaust valve opening to the atmosphere is opened so that at 12 seconds the pressure has dropped below 10 mm as depicted by curve 12. For the following 48 second time period, depicted by curve 14, no pressure is applied allowing the blood veins to refill. This cycle repeats at 60 second intervals [column 2, lines 14 through 27].

As for the pressure inside the boot, Nicholson states:

> FIG. 4 shows pressure measured inside a boot during a controller pressure cycle according to FIG. 1. The rise time inside the boot is 40 mm Hg. in approximately 4 seconds as shown in curve 35. The fall time shown by curve 36 is likewise a little slower falling to 10 mm Hg. in about 2 seconds and then curving exponentially to 0 over the next 8 seconds.
>
> While the invention has been described in accordance with a preferred embodiment, some latitude in the operation of the cycle is desirable depending on specific patients and conditions. A rapid boot pressure rise to at least 30 mm of mercury produces near optimum results when extended over 3 seconds. With particularly sensitive patients, this rise may be extended out to 5 seconds to reduce discomfort. Similarly, the maximum pressure attained is desirably between 40 and 50 mm of mercury, but a peak of 30 mm of mercury is sufficient for most cases. A range of 9 to 15 seconds is acceptable for the time interval between the beginning of pressure application and the onset of pressure release. For maximum effect

> it is desirable to delay the next application of pressure until the venous flow has returned to its normal equilibrium point, however, this differs with the individual patient and may vary within a fairly wide range with a total period between the cyclical commencement of pressure application being anywhere from about 40 to 80 seconds. A period of 60 seconds is suitable for most cases [column 2, line 67 through column 3, line 26].

In support of the appealed rejection, the examiner explains that

> [i]t would have been obvious to modify the inflation means of Dreiser with the inflation means and criteria that are taught by either Gaskell/Parrott or Nicholson et al in order that the pressure is rapidly and repeatedly applied to the foot so that the patient's blood flow is stimulated in order to combat deep-vein thrombosis. Patentees are to note that their exact parameters are considered to be obvious choices of design and experimentation in view of the teachings of Gaskell/Parrott and Nicholson et al for each of these references teaches a rapid inflation and deflation of the pressure applicator in order to assist blood flow. Also, patentees are to note that the level of pressure claimed would have been obvious for it is well known that if one wishes to increase the blood forced from the foot, one would increase the pressure level applied to the foot.
>
> It would have been obvious to modify the Dreiser inflation criteria so that the pressure is applied at periodic intervals between 20 and 60 seconds, as taught by Gaskell/Parrott, in order to provide pressure cycles having dwell periods that allow that foot to refill with blood before the next pressure cycle is begun. It would have been obvious to modify the Dreiser device with the inflation time taught by Gaskell/Parrott so that instantaneous inflation of the bladder occurs, thereby increasing the blood flow provided by the Dreiser device [final rejection, pages 4 and 5].

In the alternative, the examiner submits that the limitations in claims 7 through 9 and 11 relating to the specific operational criteria of the cyclically operable automatic means for delivering pressure within the bag are recitations of intended use which are entitled to little, if any, patentable weight (see, for example, pages 4 and 8 in the answer).

With regard to the latter point, while the criteria limitations in the appealed claims may be "functional" in nature, it is well settled that there is nothing intrinsically wrong with employing "functional" limitations to define something by what it does rather than by what it is. In re Hallman, 655 F.2d 212, 215, 210 USPQ 609, 611 (CCPA 1981); In re Swinehart, 439 F.2d 210, 213, 169 USPQ 226, 228 (CCPA 1971). Here, the criteria limitations in the appealed claims define the cyclically operable automatic means for delivering pressure by what it does. Thus, these limitations are more than mere recitations of intended use, and must be taken into account in evaluating the obviousness of the claimed subject matter as defining the structure of the automatic means for delivering pressure.

As for the reference combination proposed by the examiner, although Gaskell/Parrott and Nicholson disclose appliances comprising an inflatable boot and cyclically operable means for delivering pressure within the boot, neither teaches the cyclically operable means to be operable in accordance with all of the criteria set forth in claim 7. According to the underlying patent specification, these criteria, taken as a whole, are specifically chosen to stimulate the venous pump mechanism in the foot by replicating forces applied to the foot under normal ambulatory conditions. None of the applied references appreciates that a physiological venous pump mechanism exists in the sole of a foot, much less that this pump mechanism is naturally stimulated by normal ambulatory motion and that the conditions of such ambulatory motion can be simulated by an inflatable

device. In this light, it is not apparent, nor has the examiner cogently explained, how or why the references relied upon by the examiner would have suggested a medical appliance having a cyclically operable automatic means for delivering pressure in accordance with the specific criteria recited in claim 7 as an obvious matter of design choice. Indeed, both Gaskell/Parrott and Nicholson, with their disclosures of holding the maximum inflation pressure for at least some extent, appear to teach away from an appliance having a cyclically operable automatic means for delivering pressure which operates in accordance with the criterion required by claim 7 wherein the pressure drops at least to one seventh of the maximum pressure within approximately one second upon achievement of the maximum pressure.

Thus, the prior art evidence relied upon by the examiner to support the standing rejection of claim 7, and of claims 8, 9 and 11 which depend therefrom, fails to establish a prima facie case of obviousness with respect to the subject matter recited in these claims. This being so, it is not necessary to delve into the evidence of non-obviousness of record which is relied upon by the appellant in this appeal.

In light of the foregoing, we shall not sustain the standing 35 U.S.C. § 103 rejection of claims 7 through 9 and 11.

The decision of the examiner is reversed.

REVERSED

IAN A. CALVERT	)
Administrative Patent Judge	)
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	)
	) BOARD OF PATENT
JOHN P. McQUADE	)
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	)
	) INTERFERENCES
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